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No. 03-1610

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In The
Supreme Court of the United States

JULIAN M. WHITAKER, M.D.; DURK PEARSON; SANDY SHAW; AND THE AMERICAN ASSOCIATION FOR HEALTH FREEDOM,

Petitioners,

v.

TOMMY G. THOMPSON, SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; LESTER M. CRAWFORD, ACTING COMMISSIONER OF FOOD AND DRUGS, FOOD AND DRUG ADMINISTRATION; FOOD AND DRUG ADMINISTRATION; AND THE UNITED STATES OF AMERICA,

Respondents.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The District Of Columbia Circuit

REPLY TO BRIEF IN OPPOSITION

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INTRODUCTION

The court of appeals decided two critical questions of constitutional law at odds with this Court's precedent and that of the other circuits: (1) that a proposed health claim in a petition to the Food and Drug Administration (FDA) *that had never entered the market* was speech related to "unlawful activity" suppressible outright under the first prong of *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557, 564 (1980), and (2) that invocation of the avoidance doctrine is not warranted in the presence of a serious constitutional issue unless the court also finds "a comparatively high likelihood of unconstitutionality" or "at least some exceptional intricacy of constitutional doctrine." The court of appeals also decided a question of statutory construction at odds with this Court's precedent and that of the other circuits: (3) that FDA's interpretation of 21 U.S.C. § 343(r)(1)(B) was entitled to deference, despite the plain language of the statute and legislative intent to the contrary. Respondents have failed to rebut the conflicts of authority and the importance of this Court's review. Their brief in opposition contains material misstatements of law and of the legislative history.

If our First Amendment is to have meaning in the marketplace, consumers must be permitted to receive from willing speakers in the grocery stores, health food stores, and vitamin shops of this country accurate and complete information concerning their foods and dietary supplements. Information concerning the relationship of nutrients to disease is neither accurate nor complete unless it informs consumers of nutrient effects on the healthy and the ill, on states of wellness and illness. If a nutrient affects a symptom or disease in a beneficial or deleterious way, and a consumer is denied that information at the point of sale by government fiat, that consumer is not only denied access to truth but also to information that can guide choice over which food or dietary supplement to consume or avoid during illness.

The Respondents require each food and dietary supplement in this country to be first approved as a drug and then marketed as a drug before it may convey on the label truthful information concerning the effect of nutrients on existing disease. Drug status, however, is neither a necessary nor a sufficient substitute for the health claim approval process that Congress created as an exception for foods and dietary supplements to the drug approval process. *See* 21 U.S.C. §§ 321(g)(1), 343(r)(1)(B), 343(r)(5)(D), 343(r)(3); *see also* 136 CONG. REC. S16,609 (1990) (statement of Sen. Metzenbaum); 136 CONG. REC. S16,611 (statement of Sen. Hatch). Respondents mislead by implying that the health claim approval process does not "ensure[ ] that commercial information about products . . . is scientifically substantiated, truthful, and nonmisleading." (Br. for Resp'ts at 10). To be approved, a health claim must be scientifically substantiated, truthful, and nonmisleading. The health claim approval process requires (1) that a product meet the definition of a food or a dietary supplement, 21 C.F.R. § 101.70(f), 101.14(a)(2); (2) that it be safe for ingestion at the levels necessary to justify the claim, 21 C.F.R. § 101.14(b)(3)(ii); and (3) that any nutrient-disease relationship claim be backed by significant scientific agreement or, at a minimum, credible scientific evidence accompanied by a disclaimer sufficient to avoid misleadingness. *See* 21 U.S.C. § 343(r)(3)(B)(i); 21 C.F.R. § 101.70(f); *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999), *reh'g en banc denied*, 172 F.3d 72.

ARGUMENT

Respondents argue that the censoring of makers of unpatentable nutrients (by barring them from informing consumers through health claims of the effects of those nutrients on existing disease) is an act unreviewable under the First Amendment, should not be considered to raise a constitutional question worthy of invocation of the avoidance doctrine, and should be accepted as an act intended by Congress despite plain statutory language to the contrary and despite legislative history revealing that

Congress did not intend to limit the broad statutory language, "characterize[s] the relationship of any nutrient to a disease or a health-related condition," 21 U.S.C. § 343(r)(1)(B), to a very narrow meaning: "the role nutrition may play in reducing the risk of contracting a disease in the future." Br. for Resp'ts at 8.

1. Respondents argue that it is "constitutionally permissible" to refuse First Amendment review of Respondents' speech suppression on the grounds (a) that Petitioners' health claim petition is "evidence" of Petitioners' intent to sell an unapproved new drug and (b) that *Wisconsin v. Mitchell*, 508 U.S. 476 (1993), is controlling. Respondents misconstrue the apposite law. In this case an illegal act would be use of the Petitioners' saw palmetto health claim in the market before FDA approval or allowance. *See* 21 U.S.C. § 343(r)(1)(B). It is not illegal to write a health claim, put it in a petition, and send it to the FDA asking that agency to approve or allow the claim. Petitioners never put the saw palmetto health claim on a label or in labeling; they never entered it into the market. In the first instance, they have filed a health claim petition with FDA asking that agency to review and allow the claim. *See* Compl. ¶¶ 1-2. There is thus no illegal act to which the health claim relates. The court of appeals expanded the first prong of *Central Hudson* grossly: excluding from First Amendment review lawful petitioning of the government for a redress of a prior restraint on truthful speech. No precedent from this Court or from any other court of appeals sanctions this denial of First Amendment protection.

The court of appeals' decision chills petitioning for redress of speech bans on nutrient-disease relationship claims – an effect antithetical to core First Amendment principles that place a constitutional onus in favor of full disclosure of truthful information over its suppression. *See, e.g., Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 371 (2002); *Ibanez v. Fla. Dep't of Bus. & Prof'l Reg.*, 512 U.S. 136, 144-46 (1994); *Peel v. Attorney Registration and Disciplinary Comm'n*, 496 U.S. 91, 99-111 (1990); *Shapero v. Ky. Bar Ass'n*, 486 U.S. 466, 478 (1988); *In re R.M.J.*,

455 U.S. at 191, 203, 206 (1982); *Bates v. State Bar of Ariz.*, 433 U.S. 350, 376 (1977).

Wisconsin v. Mitchell is inapposite. In *Mitchell* there was an illegal act to which the speech related: the defendant's conviction for aggravated battery. The defendant's racist statements during trial were thus not protected against consideration as an aggravating factor in sentencing because they related to the aggravated battery. *See Wisconsin v. Mitchell*, 508 U.S. 476, 489 (1993). Here one searches in vain for an illegal act predicate. It does not exist. *Central Hudson*'s first prong does not apply, and full First Amendment review is warranted.

2. Respondents fail to address Petitioners' actual avoidance doctrine argument. Petitioners fault the court of appeals for refusing invocation of the doctrine and for heightening the doctrine's threshold requirement from a serious constitutional issue to "a comparatively high likelihood of unconstitutionality" or "at least some exceptional intricacy of constitutional doctrine." *Compare Edward J. DeBartolo Corp. v. Fla. Gulf Coast Bldg. & Contr. Trades Council*, 485 U.S. 568, 575 (1988) *with* Pet. App. at 8a-9a. This Court and the other courts of appeals have repeatedly invoked the doctrine to avoid deference to an agency's statutory interpretation when a serious constitutional issue is raised. *See, e.g., DeBartolo*, 485 U.S. at 575; *NLRB v. Catholic Bishop of Chicago*, 440 U.S. 490, 500-501 (1979); *Psinet, Inc. v. Chapman*, 362 F.3d 227, 236 (4th Cir. 2004); *United States v. Awadallah*, 349 F.3d 42, 55 (2d Cir. 2003); *United States v. Hernandez*, 314 F.3d 430 (9th Cir. 2002), *amended by* 322 F.3d 592, 602 (9th Cir. 2003); *Mahadeo v. Reno*, 226 F.3d 3, 10 (1st Cir. 2000); *George v. Nat'l Ass'n of Letter Carriers*, 185 F.3d 380, 387 (5th Cir. 1999). Censorship of a truthful nutrient-disease relationship claim raises a serious constitutional issue. The presence of that issue, and not the requirement of a "high likelihood of unconstitutionality" or "exceptional intricacy of constitutional doctrine" (as the court of appeals would have it), should have caused the court of appeals to refuse *Chevron* deference. *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984). The

Supreme Court should review this case to prevent a conflict between the court of appeals' decision and this Court's and the other circuits' avoidance doctrine precedent. This Court can thereby ensure consistent effectuation of the doctrine's purpose: preventing abdication of federal judicial review caused by deference to a federal agency's unchecked construction of the constitutionality of its own governing statute. *See Legal Servs. Corp. v. Velazquez*, 531 U.S. 533, 545 (2000) (citing *Marbury v. Madison*, 5 U.S. 137, 1 Cranch 137, 177 (1803)).

3. Respondents falsely claim that the Nutrition Labeling and Education Act (NLEA) legislative history reveals that Congress intended the health claim definition in 21 U.S.C. § 343(r)(1)(B) ("characterize[s] the relationship of any nutrient * * * to a disease or a health-related condition") to be limited in meaning to claims of risk reduction for future disease. Pub. L. No. 101-535, 104 Stat. 2353 (1990). Neither the statute's plain language nor the legislative history support that interpretation. The NLEA House Report, H.R. REP. NO. 101-538 (1990), contradicts Respondents' interpretation. *See Garcia v. United States*, 469 U.S. 70, 76 (1984) (" . . . the authoritative source for finding the Legislature's intent lies in the Committee Reports on the bill. . . .' ") (citations omitted). The NLEA House Report refers to claims of a dietary supplement's effect on existing disease as "health claims." *See e.g.*, H.R. REP. NO. 101-538 at 9 (" . . . During the mid-1980's, companies began making health claims on foods, even though the FDA had not approved the claims through the drug approval process. Those statements claimed that the food was valuable in the prevention or treatment of various diseases. . . ."). *Id.* ("[T]here is a serious question as to whether the Agency [presently] has the legal authority to implement the program that it has proposed, which would permit health claims regarding the usefulness of a food in treating a disease, without also requiring that the claim meet the premarket approval requirements applicable to drugs"). The report nowhere includes the narrow interpretation favored by Respondents. The report emphasizes Congress's concern that health claims be accurate statements of the

nutrient-disease relationship, an end frustrated by Respondents' refusal to allow health claims to convey accurate information concerning the effect of a nutrient on an existing disease. Congress expected, "[t]he regulation [authorizing a health claim to] describe . . . the significance of the nutrient in affecting [a] disease . . . " H.R. REP. NO. 101-538 at 21. Congress thus wanted the nutrient's *actual* significance to disease communicated through health claims.

Respondents ignore the NLEA House Floor Managers' Statement: "In our view, vitamins and other substances covered by this provision should be subject to at least as strong a standard as is applicable to other foods that contain claims that the food will treat a disease or health condition." 136 CONG. REC. H12,953 (October 26, 1990).

No member's statement cited by Respondents defines "health claim" as limited in meaning to claims of risk reduction for future disease. Even were there such a statement, rules of construction lead us to conclude that member statements lack the probity of the NLEA House Report and the Floor Managers' Statement. *See Garcia*, 469 U.S. at 76 ("We have eschewed reliance on the passing comments of one Member . . . and casual statements from the floor debates. . . . In *O'Brien* we stated that Committee Reports are 'more authoritative' than comments from the floor . . . ") (internal citations omitted); *see also Nat'l Ass'n of Greeting Card Publishers v. USPS*, 462 U.S. 810, 833 n.28 (1982) (Statements of House Floor Managers are only outranked by Conference and Committee Reports).

Respondents ignore the critical fact that during NLEA consideration Congress had before it FDA's preferred definition ("the value that ingestion (or reduced ingestion) of a dietary component may have in either lowering the risk, or forestalling the premature onset, of a particular chronic disease," 55 Fed. Reg. 5176, 5192 (Feb. 13, 1990)) but did not put that definition in the statute, choosing instead the far broader language appearing in 21 U.S.C. § 343(r)(1)(B). Under *INS v. Cardoza-Fonseca*, 480 U.S.

421, 442-443 (1987), Congress's failure to adopt FDA's preferred definition favors the statute's plain meaning.

Respondents also argue erroneously that when Congress commended ten nutrient-disease relationships to FDA for evaluation, Congress did so expecting FDA to limit its evaluation to the nutrients' effect on reducing the risk of those diseases. Br. for Resp'ts at 8. That is a misrepresentation. Congress ordered FDA to evaluate ten nutrients and diseases "as required by" sections 403(r)(3) [21 U.S.C. § 343(r)(3)] and 403(r)(5)(D) [21 U.S.C. § 343(r)(5)(D)] (i.e., of the "relationship" of the nutrients to the diseases). Congress did not limit FDA's assessment to disease risk reduction. In its statutory mandate, Congress listed the nutrients and diseases thusly without limiting FDA's scope of review under 21 U.S.C. §§ 343(r)(3), 343(r)(5)(D): calcium and osteoporo sis, dietary fiber and cancer, lipids and cardiovascular disease, lipids and cancer, sodium and hypertension, dietary fiber and cardiovascular disease, folic acid and neural tube defects, antioxidant vitamins and cancer, zinc and immune function in the elderly, and omega-3 fatty acids and heart disease. *See* Sec. 3(b)(1)(A)(vi), (x) of NLEA, Pub. L. No. 101-535, 104 Stat. 2353 (1990).

Respondents suggest that because claims of an effect on existing disease are permitted for "medical foods" under the Food Drug and Cosmetic Act (FDCA), they should not be understood as permitted in health claims. *See* Br. for Resp'ts at 8-9. The argument is a non sequitur, and there is neither statutory language nor legislative history to support it. The medical foods and health claims provisions of the FDCA are distinct exemptions from the definition of a drug. That Congress authorizes use of treatment claims for medical foods does not preclude the use of claims concerning the effect of nutrients on existing disease under the health claims provision. Respondents misrepresent the meaning of "medical foods" in the FDCA. Congress created "medical foods" to address the special dietary needs of Americans with rare diseases who suffer digestion and absorption incapacities and are under physician supervision. *See* 134 CONG. REC. S6210-13 (March 31,

1988); *see also* 21 U.S.C. § 360ee. Only a small subset of foods and dietary supplements qualify as medical foods.

By contrast, Congress intended the NLEA health claims provision to apply to all conventional foods and dietary supplements. The health claims provision was to provide the public with accurate information about the nutrient-disease relationship on the labels and in the labeling of foods and dietary supplements sold direct to consumers without physician supervision. *See* H.R. REP. NO. 101-538 (1990). Thus, the purpose of health claims is to inform consumers at the point of sale of nutrient-disease relationships, not to provide physicians with information necessary for the dietary management of people under their care who have distinctive nutritional requirements arising from rare diseases.

When Congress enacted the NLEA in 1990, it elected not to subject medical foods to the health claims requirements it then created for conventional foods and dietary supplements. *See* 21 U.S.C. § 403(q)(5)(A)(iv); *see also* 61 Fed. Reg. 60661, 60663 (Nov. 29, 1996). That decision does not in any way reveal an intent on the part of Congress to limit claims of a nutrient's effect on existing disease to medical foods.

The Respondents argue that the statute as a whole supports their statutory constriction of "health claims." Br. for Resp'ts at 8. Read in light of its legislative history, the statute does not support the Respondents' position. Nothing in the statute or in the legislative history demonstrates that Congress meant "health claims" to have the meaning Respondents give that term. 21 U.S.C. § 321(ff) defines a dietary supplement by reference to its content (a vitamin, mineral, herb, botanical, etc.), its form, method of ingestion, and labeling. 21 U.S.C. § 343(r)(1)(B) defines health claims for foods and dietary supplements. 21 U.S.C. § 343(r)(3)(B) defines a standard for the scientific evaluation of health claims separate from the drug approval process. 21 U.S.C. § 343(r)(5)(D) grants FDA authority to develop a standard and procedure for the evaluation of the validity of dietary

supplement health claims. By regulation, FDA adopted the health claim standard for foods as the one to be applied to dietary supplements. *See* 21 C.F.R. § 101.14(g).

21 U.S.C. § 321(g)(1)(B), in pertinent part, defines drugs as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals," but the second to the last sentence of the section excepts foods and dietary supplements from categorization as drugs if they bear FDA authorized or allowed health claims, providing: "A food or dietary supplement for which a claim, subject to . . . [21 U.S.C. § 343(r)(1)(B)] and . . . [21 U.S.C. § 343(r)(3)] [for foods] or . . . [21 U.S.C. § 343(r)(1)(B)] and . . . [21 U.S.C. § 343(r)(5)(D)] [for dietary supplements], is made in accordance with the requirements of [21 U.S.C. § 343(r)] is not a drug solely because the label or the labeling contains such a claim." Read in the light of the legislative history, it is clear that Congress did not intend the word "solely" in that section to grant FDA interpretive authority to circumscribe the health claims definition. *See generally* H.R. REP. NO. 101-538 (1990). Rather, Congress meant to exempt foods and dietary supplements carrying FDA approved or allowed health claims from categorization as unapproved new drugs. But Congress did not mean the exemption to prohibit drug classification if the party in question were to, for example: (1) sell the product for intravenous injection rather than oral ingestion (that would make the product a drug by method of administration because a dietary supplement, by definition, must be ingested, 21 U.S.C. §§ 321(ff)(2)(A)(i), 350(c)(1)(B)(i)); (2) put on the label or in the labeling a nutrient-disease relationship claim other than the one allowed or approved by FDA under the health claims review process; or (3) sell the product aware that it was in fact being used for treatment of a disease other than the one within the nutrient-disease relationship claim allowed or approved by FDA in labeling.

CONCLUSION

If the First Amendment is to have meaning in the grocery stores, health food stores, and vitamin shops of this country, truth must be allowed to be communicated on food and dietary supplement labels and in their labeling. Petitioners and consumers are entitled to the whole truth: an accurate and complete description of how the nutrients in the products Petitioners sell affect health and disease. Respondents lock truth out of the market to the detriment of Petitioners and consumers alike. This Court should return the law to its constitutional moorings. It should reaffirm that the First Amendment is a barrier to government censorship of truthful information, that disclosure is to be preferred over suppression, and that the Respondents' proper, constitutional resort is to reasonable disclaimers and the provision of more information rather than to censorship. For the reasons in the petition and this reply, Petitioners respectfully request that the Supreme Court grant a writ of certiorari, reverse the decision below, and order that the Petitioners' health claim be processed by the FDA.

Respectfully submitted,

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